Patient Safety
September, 2003

1: Am Heart J. 2003 Sep;146(3):431-8.
Ximelagatran compared with warfarin for prevention of thromboembolism in patients with nonvalvular atrial fibrillation: Rationale, objectives, and design of a pair of clinical studies and baseline patient characteristics (SPORTIF III and V).
Halperin JL; Executive Steering Committee, SPORTIF III and V Study Investigators.
Zena and Michael A. Wiener Cardiovascular Institute, Mount Sinai Medical Center, New York, NY 10029-6574, USA. jonathan.halperin@msnyuhealth.org
BACKGROUND: Ximelagatran is a novel, oral direct thrombin inhibitor under investigation as an alternative to warfarin for prevention of thromboembolism in patients with nonvalvular atrial fibrillation (AF). Two long-term studies in patients with AF and at least one additional risk factor for stroke are underway to compare the safety and efficacy of fixed-dose ximelagatran (36 mg bid) without coagulation monitoring with dose-adjusted warfarin (international normalized ratio 2.0-3.0). METHODS: SPORTIF III is a randomized, open-label, parallel-group study with blinded event assessment involving 3407 patients at 259 sites in 23 countries. SPORTIF V is similar, but with double-blind treatment allocation involving 3922 patients at 409 North American sites. The primary end point in each study is the incidence of all strokes and systemic embolic events, and the objective is to establish the noninferiority of ximelagatran relative to warfarin. Secondary end point constellations include (1) death, stroke, systemic embolism, and myocardial infarction; (2) ischemic stroke, transient ischemic attack, and systemic embolism; and (3) bleeding and treatment discontinuation. Blinded central committees adjudicate all end points and monitor patient safety. The studies commenced July 2000; enrollment ended in December 2001. Each study will accrue > or =4000 patient-years and > or =80 primary end points with a minimum per-patient exposure of 12 months. Combined analysis of both studies is also planned. RESULTS: The demographics of the 2 patient populations are similar and should allow the studies to meet the objective. CONCLUSIONS: The program, the largest conducted in this indication, will determine the safety and antithrombotic efficacy of ximelagatran as an alternative to warfarin for prevention of thromboembolism in patients with AF.
PMID: 12947359 [PubMed - in process]

2: Am J Med. 2003 Aug 18;115 Suppl 3A:201S-210S.
A critical review of endoscopic therapy for gastroesophageal reflux disease.
Hogan WJ, Shaker R.
Medical College of Wisconsin, Milwaukee 53226, USA.
The US Food and Drug Administration has approved 2 endoscopic devices for

treating gastroesophageal reflux disease, and several thousand procedures have been performed to date. At least 6 other endoscopic devices designed to treat gastroesophageal reflux are in various stages of testing and may soon obtain approval for clinical use. Short-term follow-up studies uniformly report improvement in heartburn symptoms and quality-of-life scores, as well as decreases in use of antisecretory medications. However, esophageal acid reflux is not normalized after these treatments, nor is esophagitis improved. Although troubling efficacy and safety issues are currently unresolved, these techniques are becoming routine clinical procedures outside of clinical trials. Unless there is rigorous attention to scientific validation of these techniques, including comparative trials versus conventional treatments, there will remain a cloud of doubt and concern about their role and usefulness in clinical medicine. The rapid incursion of these devices into the clinical marketplace before they have undergone critical scientific scrutiny magnifies the urgency of addressing these issues.
Publication Types:
Review
Review, Tutorial
PMID: 12928102 [PubMed - indexed for MEDLINE]

3: Anaesthesia. 2003 Sep;58(9):833-4.
Patient safety and quality: can anaesthetists play a greater role?
Jorm C.
Sydney, Australia.
PMID: 12911352 [PubMed - in process]

4: Anesthesiology. 2003 Sep;99(3):652-5.
Bacterial reduction by cell salvage washing and leukocyte depletion filtration.
Waters JH, Tuohy MJ, Hobson DF, Procop G.
Section of Anesthesia for Obstetrics & Gynecology, Department of General Anesthesiology, Cleveland Clinic Foundation, Ohio 44195, USA. watersj@ccforg
BACKGROUND: Blood conservation techniques are being increasingly used because of
the increased cost and lack of availability of allogeneic blood. Cell salvage offers great blood savings opportunities but is thought to be contraindicated in a number of areas (e.g., blood contaminated with bacteria). Several outcome studies have suggested the safety of this technique in trauma and colorectal surgery, but many practitioners are still hesitant to apply cell salvage in the face of frank bacterial contamination. This study was undertaken to assess the efficacy of bacterial removal when cell salvage was combined with leukocyte depletion filtration. METHODS: Expired packed erythrocytes were obtained and inoculated with a fixed amount of a stock bacteria (Escherichia coli American Type Culture Collections [ATCC] 25922, Pseudomonas aeruginosa ATCC 27853, Staphylococcus aureus ATCC 29213, or Bacteroides fragilis ATCC 25285) in amounts ranging from 2,000 to 4,000 colony forming units/ml. The blood was processed via a cell salvage machine. The washed blood was then filtered using a leukocyte reduction filter. The results for blood taken during each step of processing were compared using a repeated-measures design. RESULTS: Fifteen units of blood were contaminated with each of the stock bacteria. From the prewash sample to the postfiltration sample, 99.0%, 99.6%, 100%, and 97.6% of E. coli, S. aureus, P. aeruginosa, and B. fragilis were removed, respectively. DISCUSSION: Significant but not complete removal of contaminating bacteria was seen. An increased level of patient safety may be added to cell salvage by including a leukocyte depletion filter when salvaging blood that might be grossly contaminated with bacteria.

PMID: 12960550 [PubMed - in process]

5: Ann Emerg Med. 2003 Aug;42(2):285-6.
Air bag-related injuries.
Martinez R.
Departmemnt of Emergency Medicine, School of Medicine, Emory University, Atlanta, GA, USA.
PMID: 12883518 [PubMed - indexed for MEDLINE]

6: Ann Health Law. 2003 Summer;12(2):179-234, table of contents.
The hospital board at risk and the need to restructure the relationship with the medical staff: bylaws, peer review and related solutions.
Marren JP, Feazell GL, Paddock MW.
Hogan Marren, Ltd., Chicago, Illinois, USA.
This article argues that the current structure of the hospital governing board and medical staff relationship does not support and promote quality and patient-centered care. The fundamental flaw in the current structure is the interdependent, yet independent and discordant relationships between hospital governing boards and medical staffs. These relationships are described as cultures and fit into three types of "silos": organizational (the "structural silo"); professional (the "professional silo", including the "culture of blame"); and the fragmented quality information silo (the "informational silo"). While case law, statutory requirements and regulatory expectations clearly state that governing boards are ultimately responsible for quality of patient care, governing boards delegate these functions to medical staff without having sufficient information to measure and monitor quality. As a result, problems manifest because of these failures of oversight and compliance. Dramatic lapses in quality occur due to overuse, underuse, and misuse of healthcare services. Furthermore, the challenges and opportunities from improved quality and patient safety, as a strategic business driver, cannot be seized until the underlying structural flaws are understood and addressed. This article proposes that solutions become apparent when the various health care constituencies are educated about these cultural impacts and when multidisciplinary bodies, with board leadership and direct authority, integrate and consider quality information.
Publication Types:
Legal Cases
PMID: 12856456 [PubMed - indexed for MEDLINE]

7: Ann Intern Med. 2003 Aug 19;139(4):267-73.
Patient safety and medical malpractice: a case study.
Brennan TA, Mello MM.
Harvard School of Public Health, Harvard Medical School, and Brigham and Women's Hospital, Boston, Massachusetts 02115, USA.
The system of tort liability for medical malpractice is frequently criticized for poorly performing its theoretical functions of compensating injured patients, deterring negligence, and dispensing corrective justice. Working from an actual malpractice case involving serious injury but no apparent negligence, the authors explore these criticisms from the perspectives of both the plaintiff-patient and the defendant-physician. They then examine the tort system through the lens of patient safety and conclude that the tensions between the system and patient safety initiatives suggest a need to reexamine our attachment to adversarial dispute resolution in health care. They propose targeted reforms that could improve the functioning of the system and create incentives to improve safety and quality.

Publication Types:
Clinical Conference
PMID: 12965982 [PubMed - in process]

8: Arch Surg. 2003 Sep;138(9):991-5.
Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers.
Vila H Jr, Soto R, Cantor AB, Mackey D.
Department of Anesthesiology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL 33612, USA.
HYPOTHESIS: This study compared outcomes to determine whether patient safety is similar in Florida ambulatory surgery centers and offices. DATA SOURCES: All adverse incident reports to the Florida Board of Medicine for procedure dates April 1, 2000, to April 1, 2002 were reviewed. The numbers of office procedures performed during a 4-month period were used to estimate the total number of procedures. Ambulatory surgery death summaries, adverse incident data, and volumes of procedures for 2000 were procured from the Florida Agency for Health Care Administration. STUDY SELECTION/DATA EXTRACTION: Adverse incident reports
were reviewed by multiple parties; only reports that involved an office surgical procedure and resulted in injury or death were included in the outcomes calculation. Reports were extracted independently by multiple reviewers. DATA SYNTHESIS: Adverse incidents occurred at a rate of 66 and 5.3 per 100,00 procedures in offices and ambulatory surgery centers, respectively. The death rate per 100,000 procedures performed was 9.2 in offices and 0.78 in ambulatory surgery centers. The relative risks for injuries and deaths for office procedures vs ambulatory surgery centers were 12.4 (95% confidence interval, 9.5-16.2) and 11.8 (95% confidence interval, 5.8-24.1), respectively. CONCLUSIONS: In this review of surgical procedures performed in offices and ambulatory surgery centers in Florida during a recent 2-year period, there was an approximately 10-fold increased risk of adverse incidents and death in the office setting. If all office procedures had been performed in ambulatory surgery centers, approximately 43 injuries and 6 deaths per year could have been prevented.
PMID: 12963657 [PubMed - in process]

9: Clin Infect Dis. 2003 Sep 15;37(6):764-71. Epub 2003 Aug 27.
Vascular catheter site care: the clinical and economic benefits of chlorhexidine gluconate compared with povidone iodine.
Chaiyakunapruk N, Veenstra DL, Lipsky BA, Sullivan SD, Saint S.
Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, 98195-7630, USA. (veenstra@u.washington.edu)
The use of chlorhexidine gluconate solution for vascular catheter insertion site care reduces the risk of catheter-related bloodstream infection by one-half, compared with povidone iodine. Our objective was to evaluate the cost-effectiveness of chlorhexidine gluconate versus povidone iodine. We used data from randomized, controlled trials, meta-analyses, and epidemiologic studies to construct a decision analysis model. We estimated that use of chlorhexidine, rather than povidone, for central catheter site care resulted in a 1.6% decrease in the incidence of catheter-related bloodstream infection, a 0.23% decrease in the incidence of death, and savings of $113 per catheter used. For peripheral catheter site care, the results were similar, although the differences were smaller. The results were found to be robust on multivariate sensitivity analyses. Use of chlorhexidine gluconate in place of the current

standard solution for vascular catheter site care is a simple and cost-effective method of improving patient safety in the hospital setting.
PMID: 12955636 [PubMed - in process]

10: Emerg Med J. 2003 Sep;20(5):402-405.
Emergency department overcrowding in the United States: an emerging threat to patient safety and public health.
Trzeciak S, Rivers EP.
Department of Emergency Medicine and the Section of Critical Care Medicine, Robert Wood Johnson Medical School at Camden, University of Medicine and Dentistry of New Jersey, Cooper Health System, Camden, USA. Departments of Emergency Medicine and Surgery, Henry Ford Hospital, Case Western Reserve University, Detroit, USA.
Numerous reports have questioned the ability of United States emergency departments to handle the increasing demand for emergency services. Emergency department (ED) overcrowding is widespread in US cities and has reportedly reached crisis proportions. The purpose of this review is to describe how ED overcrowding threatens patient safety and public health, and to explore the complex causes and potential solutions for the overcrowding crisis. A review of the literature from 1990 to 2002 identified by a search of the Medline database was performed. Additional sources were selected from the references of the articles identified. There were four key findings. (1) The ED is a vital component of America's health care "safety net". (2) Overcrowding in ED treatment areas threatens public health by compromising patient safety and jeopardising the reliability of the entire US emergency care system. (3) Although the causes of ED overcrowding are complex, the main cause is inadequate inpatient capacity for a patient population with an increasing severity of illness. (4) Potential solutions for ED overcrowding will require multidisciplinary system-wide support.
PMID: 12954674 [PubMed - as supplied by publisher]

11: Expert Opin Drug Saf. 2002 Sep;1(3):269-74.
A safety look at currently available statins.
Moghadasian MH.
Division of Toxicological Studies, PhenoPharma Research, Inc, St Paul's Hospital and University of British Columbia, 180-1081 Burrard Street, Vancouver, BC, Canada V6Z 1Y6. mhmoghad@interchange.ubc.ca
In this mini-review, the evidence for safety and efficacy of currently available statins is discussed. Large-scale, long-term clinical studies have documented an outstanding efficacy and safety profile for statin monotherapy when used at pharmacological doses. Non-life-threatening side effects may occur in up to 15% of patients receiving one statin. Sporadic reports show possible adverse effects of statins on nervous system function including mood alterations. More serious side effects may also occur but at much lower rates. Significant elevations in the activity of serum aminotransferase and creatine kinase alone or in combination with muscle pain in statin-treated patients should be taken seriously; under these conditions, monitoring the statin dose or its discontinuation must be considered. Unlike monotherapy, combination therapy is more problematic. Particularly, combination of the statins with gemfibrozil results in higher rates of drug toxicity. Co-administration of statins with other drugs, especially those which may interfere with the cytochrome P450 system, should be considered carefully. Special attention must be paid to the tolerability of the statins in elderly and transplant patients. The safety of statins in children and adolescents has not yet been well-documented, thus, statin therapy is not routinely recommended in this group of hyperlipidaemic

subjects. Future clinical studies and surveillance information will warrant long-term safety of each member of this class of lipid-lowering agents.
Publication Types:
Review
Review, Tutorial
PMID: 12904142 [PubMed - indexed for MEDLINE]

12: Health Care Manag (Frederick). 2003 Jul-Sep;22(3):211-8.
Strategies to decrease medication errors.
Davidhizar R, Lonser G.
Division of Nursing, Bethel College, 1001 West McKinley Avenue, Administration Building, Room 221, Mishawaka, IN 46545, USA.
Medication errors present a significant hazard to patient safety and have been increasingly in the news as studies correlate the nursing shortage and patient death. This article discusses strategies to decrease medication errors and increase patient safety during medication administration.
MID: 12956222 [PubMed - in process]
50: Health Phys. 2003 Aug;85(2 Suppl):S15-9.
A reassessment of radioactive material security in health care and biomedical research.
Leidholdt EM Jr, William GE, McGuire LE.
VHA National Health Physics Program (115HP/NLR), U.S. Department of Veterans Affairs, 2200 Fort Roots Drive, North Little Rock, AR 72114, USA.
edwin.leidholt@med.va.gov
The medical facilities of the U.S. Department of Veterans Affairs (VA) use radioactive material for health care and biomedical research. In the past, a single level of security for all radioactive material was generally deemed to be adequate. The events of 11 September 2001 prompted a reassessment of security. Based on site visits to VA facilities possessing a range of radioactive material typically used in health care and biomedical research, the VA National Health Physics Program has compiled recommendations for the security of radioactive material. A primary recommendation is to evaluate radioactive material from a risk perspective and use security measures commensurate with risk. The risk evaluation should consider activity, half-life, exposure rate constant, ALI, ease of removal/portability, and dispersibility. We concluded that current security measures are likely adequate for the risks associated with most nuclear medicine departments and biomedical research laboratories. However, for radioactive material of higher risk, particularly multicurie sources of long half-life, the radiation safety staff should consult with police/security experts to determine if additional security measures are warranted. This focus on risk should help optimize resource allocation. We also recommend that security evaluations consider both physical security and personnel security, training of staff with unescorted access to higher-risk radioactive material emphasize security issues, and disposal of higher-risk material not likely to be used. Finally, we note that the goals of security can be in conflict with hazard awareness and hazard communication.
PMID: 12865744 [PubMed - indexed for MEDLINE]

13: Healthcare Benchmarks Qual Improv. 2003 Aug;10(8):92-3.
Nurses and pharmacists partner for patient safety.
[No authors listed]
Professions face serious challenge of work force shortages. Leaders of five organizations come together in first step of ambitious journey. Revolutionary changes, not quick fixes, seen as solution.
PMID: 12901320 [PubMed - indexed for MEDLINE]

14: Healthcare Benchmarks Qual Improv. 2003 Aug;10(8):93-4.
JCAHO OKs alternative safety goal approaches.
[No authors listed]
PMID: 12901321 [PubMed - indexed for MEDLINE]

15: Hosp Health Netw. 2003 Aug;77(8):21-2.
Medication safety issue brief. Change your culture forever. Series II, Part 3.
American Hospital Association; American Society of Health-System Pharmacists; Hospitals & Health Networks.
What is it they say about the best-laid plans? They often go awry. It's the same with initiatives to make drug delivery in hospitals safer. An organization can analyze its procedures with the most sophisticated methods and squeeze out every possible chance for error, but the new design will mold with disuse if momentum is lost. There are many ways for an innovation to get derailed: lost enthusiasm, personnel changes, budget cuts. As they mature in the safety process, organizations have to be flexible but also stay firm in maintaining medication safety as a top priority. Keep safety initiatives alive by involving staff, "hardwiring" changes into the system and monitoring their progress well into the future.
PMID: 12959093 [PubMed - indexed for MEDLINE]

16: Hosp Peer Rev. 2003 Sep;28(9):117-20.
JCAHO revisits patient safety goals: what your facility must do to comply.
[No authors listed]
PMID: 12953362 [PubMed - in process]

17: Hosp Peer Rev. 2003 Aug;28(8):113-5.
Don't impairments jeopardize patient safety.
Spath P.
Brown-Spath & Associates, Forest Grove, OR, USA.
PMID: 12884485 [PubMed - indexed for MEDLINE]

18: Int J Qual Health Care. 2003 Aug;15(4):287-99.
Rethinking quality in the context of persons with disability.
Lawthers AG, Pransky GS, Peterson LE, Himmelstein JH.
Center for Health Policy and Research, University of Massachusetts Medical School, Shrewsbury, MA 01545, USA. ann.lawthers@umassmed.edu
OBJECTIVE: To review the current health services literature related to quality of care for persons with disabilities and to highlight the need for a unique framework for conceptualizing quality and patient safety issues for this population. DESIGN: Drawing on quality measurement theory, we formulate a multi-dimensional model of quality of care for persons with disability. This model is then used to identify and summarize findings from existing health services research that relate to the quality, of care for persons with disability. STUDY SELECTION: We searched MEDLINE and other databases for primary
research and review articles containing the phrases 'quality of care', 'patient safety', 'access', 'patient experience', and 'coordination of care' in conjunction with the words 'disability' or 'impairment'. RESULTS: A review of health services research suggests several potential issues in the areas of clinical quality, access, client experience, and coordination. Physical barriers, transportation, communication difficulties, and client and provider attitudes present barriers to receiving appropriate client-centered care. Communication difficulties between provider and client may increase risk for

accidental injury and decrease the quality of the client experience. Frequent contact with the health care system and the complexity of an individual's situation also increase the risk of accidental injury. Coordination, the 'lubricant' that facilitates links for all areas of quality for a person with disability, presents the most significant opportunity for improvement, because multiple medical and social providers are typically involved in the care of individuals with disabling conditions. CONCLUSION: Health care providers need to embrace a multi-disciplinary approach to quality to meet the needs of persons with disabilities. Funders and purchasers need to provide flexibility in funding to enable a comprehensive primary care approach, while health service researchers need to adopt a broad view of quality to capture issues of importance for persons with disabilities.
PMID: 12930044 [PubMed - in process]

19: Int J Qual Health Care. 2003 Aug;15(4):275-7.
Nurse staffing and patient safety: current knowledge and implications for action.
Needleman J, Buerhaus P.
Publication Types:
Editorial
PMID: 12930041 [PubMed - in process]

20: J Oral Maxillofac Surg. 2003 Sep;61(9):981-2.
Patient safety in anesthesia practice: Partnerships that make the impossible routine.
Assael LA.
PMID: 12966470 [PubMed - in process]

21: JAMA. 2003 Aug 20;290(7):905-11.
Comment in:
JAMA. 2003 Aug 20;290(7):950-1.
Pediatric drug labeling: improving the safety and efficacy of pediatric therapies.
Roberts R, Rodriguez W, Murphy D, Crescenzi T.
Office of Counter-Terrorism and Pediatric Drug Development, Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, Md 20855, USA. robertsr@cder.fda.gov
CONTEXT: Approximately 50% to 75% of drugs used in pediatric medicine have not been studied adequately to provide appropriate labeling information. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which encouraged pediatric drug development by providing an incentive in the form of additional marketing exclusivity. OBJECTIVE: To identify new drug labeling information from pediatric studies submitted to the FDA in response to written requests. DESIGN AND SETTING: Between July 1998 and April 1, 2002, the FDA requested studies on 242 drugs, and 53 drugs were granted exclusivity. As of January 2003, 49 drugs have new labels. Data from the studies of the first 33 drugs with new pediatric information on the label as of April 2002 are included. Significant labeling information was analyzed along with baseline data and types of studies requested. MAIN OUTCOME MEASURES: Safety data and pediatric information for labeled drugs. RESULTS: There were 53 studies for 33 drug products, 12 (23%) were evaluated for safety only; 23 (43%), safety and efficacy; and 18 (34%), pharmacokinetics and/or pharmacodynamics. Significant new dosing and/or safety information was identified for 12 (36%) drugs. New dosing information was determined for 7 of these drugs. Safety information was defined for gabapentin, propofol, sevoflurane, the combination of ribavirin and

interferon alfa-2b, and various betamethasone-containing dermatologic preparations. There was a higher percentage of deaths reported with patients who received propofol compared with controls in the pediatric intensive care unit. Seizures were seen in patients administered sevoflurane. Patients receiving a combination of ribavirin and interferon alfa-2b experienced an increased incidence of suicidal ideation when compared with adults. An unexpectedly high percentage of those receiving betamethasone-containing dermatologic preparations had documented hypopituitary-adrenal axis suppression. CONCLUSION: The FDAMA has
stimulated pediatric clinical studies resulting in improved understanding of the pharmacokinetics of drugs prescribed in pediatric medicine, important dose changes, and improved safety for children taking certain drugs.
Publication Types:
Evaluation Studies
PMID: 12928467 [PubMed - indexed for MEDLINE]

22: Jt Comm J Qual Saf. 2003 Aug;29(8):383-90.
Creating an integrated patient safety team.
Gandhi TK, Graydon-Baker E, Barnes JN, Neppl C, Stapinski C, Silverman J, Churchill W, Johnson P, Gustafson M.
Brigham and Women's Hospital, Boston, USA. tgandhi@partners.org
CREATING A PATIENT SAFETY TEAM: In May 2001 Brigham and Women's Hospital (Boston) created the Patient Safety Team, which was incorporated into the pre-existing safety and quality infrastructure. ESTABLISHING THE PATIENT SAFETY TEAM'S GOALS AND INITIATIVES: The goal was to create the safest possible environment for patients and staff by creating a culture of safety, increasing the capacity to measure and evaluate processes, committing to change unsafe processes, and adopting new technologies. To achieve this mission, the following initiatives were established: create a culture of safety, increase event identification, improve event analysis, close the feedback loop, assess risk proactively, improve medication safety, and involve the patient. DISCUSSION: Integrating the Patient Safety Team into pre-existing committees and departments facilitated its work while helping to reinforce the multidisciplinary nature of safety efforts. It is critical that pre-existing groups feel that patient safety represents value added and is not a threat to their current roles. SUMMARY AND CONCLUSIONS: If a patient safety strategy and team are to be effective, commitment from the organization's leaders is essential. This team should also work with individual departments and pre-existing quality structures to drive changes to the systems of care to enable health care to become as safe as possible.
PMID: 12953602 [PubMed - in process]

23: Jt Comm J Qual Saf. 2003 Aug;29(8):391-400.
What do we know about medication errors in inpatient psychiatry?
Grasso BC, Rothschild JM, Genest R, Bates DW.
Institute for Self-Directed Care, Portland, Maine, USA. bgrasso1@maine.rr.com
BACKGROUND: Adverse drug events (ADEs) have been implicated as a cause of substantial morbidity and mortality. Psychiatrists have successfully characterized one category of ADE--adverse drug reactions (ADRs), which have been studied from a medication-specific psychopharmacology frame of reference. The literature on ADEs, both preventable and nonpreventable, was reviewed within the broader patient safety framework. METHODS: English-language studies involving ADEs and medication errors in psychiatry for 1996 through 2003 were identified on MEDLINE and by using a hand search of bibliographies. RESULTS: Few reports on the incidence and characteristics of medication errors in psychiatric

hospitals could be found. Psychiatrists may not be sufficiently aware of the harm caused by errors, methodological issues regarding error detection, the validity of reported medication error rates, and the challenge of creating a nonpunitive error-reporting culture. PREVENTION STRATEGIES: Application of a systems-oriented approach to ADE reduction and the promotion of a nonpunitive culture are essential. Clinical and pharmacy staff could monitor the literature for published reports of preventable adverse events and review those reports in multidisciplinary team meetings. CONCLUSIONS: Psychiatry would benefit from learning about the terminology used in describing medication errors and ADEs. Relatively few data are available regarding the frequency and consequences of medication errors in psychiatry; more research is needed.
PMID: 12953603 [PubMed - in process]

24: Jt Comm J Qual Saf. 2003 Aug;29(8):401-8.
Microsystems in health care: Part 6. Designing patient safety into the microsystem.
Mohr JJ, Barach P, Cravero JP, Blike GT, Godfrey MM, Batalden PB, Nelson EC.

25: Jt Comm J Qual Saf. 2003 Aug;29(8):434-9, 381.
Using aggregate root cause analysis to improve patient safety.
Neily J, Ogrinc G, Mills P, Williams R, Stalhandske E, Bagian J, Weeks WB.
Veterans Health Administration (VHA) National Center for Patient Safety (NCPS), White River Junction VA Medical Center (VAMC), White River Junction, Vermont, USA.
The authors describe use of aggregate root cause analysis, which provides a systematic process for analyzing high-priority, frequent events.
PMID: 12953608 [PubMed - in process]

26: Jt Comm J Qual Saf. 2003 Aug;29(8):425-33.
The role of the private sector in monitoring health care quality and patient safety.
Blewett LA, Parente ST, Peterson E, Finch MD.
Division of Health Services Research and Policy, School of Public Health, University of Minnesota, Minneapolis, USA. blewe001@umn.edu
BACKGROUND: As payers, purchasers, and providers, both the public and private sectors have a stake in developing sound methods of measuring health care quality and patient safety. However, the role of the private sector in a national quality monitoring system remains largely underdeveloped. PRIVATE SECTOR ROLE IN HEALTH CARE QUALITY MONITORING: There have been some attempts to
pool private-sector data through health care industry efforts to measure and monitor the quality of health care services. Yet despite a number of public/private partnerships, no standard method exists for measuring and monitoring health care quality and safety across public and private payers. THE AHRQ WORKSHOP ON PRIVATE-SECTOR QUALITY MONITORING: The Agency for Healthcare
Research and Quality (AHRQ) sponsored a workshop in fall 2000 to address the private sector's role in monitoring quality in the health care system. National experts developed a conceptual framework and recommendations on the design and scope of a private-sector data monitoring system. Ten key attributes of the monitoring system, such as timeliness of reports, flexibility, efficiency, and linkability, were identified. Barriers and gaps to the development of such a system include the cost of data collection, the diversity of the units of data collection, data privacy, and limitations of administrative data elements. SUMMARY: A comprehensive, public/private data collection system would address

the multidimensional nature of quality and use data to effectively represent this complexity to the extent possible.
PMID: 12953607 [PubMed - in process]

27: Jt Comm Perspect. 2003 Aug;23(8):7.
Scoring modified for 2004 JCAHO National Patient Safety Goals.
[No authors listed]
PMID: 12920780 [PubMed - in process]

28: N Engl J Med. 2003 Aug 14;349(7):629-30.
Comment on:
N Engl J Med. 2003 Apr 3;348(14):1393-401.
Trial design and patient safety--the debate continues.
Steinbrook R.
Publication Types:
Comment
PMID: 12917298 [PubMed - indexed for MEDLINE]

29: Physician Exec. 2001 Sep-Oct;27(5):40-5.
True patient safety begins at the top. Leaders at one large health system rally around safety, avoid blame game.
White JP, Ketring SD.
INTEGRIS Health, Oklahoma City, USA.
Making patient safety the No. 1 priority at a hospital or clinic sounds like a easy task. It isn't. At one Oklahoma health system, an improved patient safety program is a massive effort requiring input and participation from every member of the staff. Figuring out how to convince employees that patient safety is their first priority means developing an extensive communication and education program.
PMID: 12881904 [PubMed - in process]

30: Plast Reconstr Surg. 2003 Sep;112(3):871-2.
Venous thromboembolism in cosmetic plastic surgery: maximizing patient safety.
Rohrich RJ, Rios JL.
PMID: 12960870 [PubMed - in process]

31: Qual Saf Health Care. 2003 Aug;12(4):291-4.
Less is (sometimes) more in cognitive engineering: the role of automation technology in improving patient safety.
Vicente KJ.
Department of Mechanical & Industrial Engineering ,University of Toronto, Ontario, Canada. vicente@mie.utoronto.ca
PMID: 12897363 [PubMed - in process]

32: Seizure. 2003 Oct;12(7):413-443.
Measuring the efficacy of antiepileptic drugs.
MOHANRAJ R, BRODIE MJ.
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Clinical trials of new antiepileptic drugs (AEDs) include regulatory studies aimed at demonstrating efficacy and reasonable safety, post-marketing open-open label studies and longer term outcome studies. Regulatory trials involve a carefully selected population of patients and are conducted under rigorously standardised conditions. Data from such studies cannot often be translated into clinical practice. Pragmatic post-marketing studies using flexible dosing

schedules allow clinicians to better judge the utility of the new drug in a wider population of patients with epilepsy and decide the most appropriate dosing schedules. This paper discusses some of the issues surrounding the measurement of efficacy of new AEDs in both pre- and post-marketing phases of their development.All of the newer AEDs are initially used in patients with refractory partial seizures as adjunctive treatment. These trials are generally parallel-group studies although cross-over designs have been employed. The use of placebo-control is uncontroversial in this type of study. Efficacy endpoints are generally manipulations of seizure frequency on study drug compared to control. Global outcome measures and health related quality of life scores can also be used to measure efficacy.As the standard AEDs are associated with a high rate of seizure remission in patients who receive them as monotherapy, demonstration of superior efficacy of a new agent in a comparative trial will require large numbers of patients in a design that takes into account the natural history of treated epilepsy. Comparing investigational agents to a standard AED in an 'active-control' study with demonstration of equivalent efficacy would seem to be an acceptable way of assessing efficacy of new AEDs in this population. Some regulators, however, do not accept equivalence as proof of efficacy and insist on demonstration of superiority compared to a control. The use of placebo alone in the control group is ethically dubious. Several innovative study designs have, therefore, been used to satisfy regulatory requirements, while maintaining patient safety including withdrawal to monotherapy using high versus low dose comparators.Observational outcome studies provide the best opportunity of exploring the long-term utility of individual AEDs. Such studies largely follow standard clinical practice and need considerable time and resources. They can, however, yield valuable information about the effectiveness of AEDs in everyday clinical practice. Data from regulatory trials should be complemented by postmarketing studies and longer term studies of outcome to help clinicians decide the best way of utilising new AEDs and establishing their role in the therapeutic armamentarium.
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